

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA**

CHARLESTON DIVISION

KATHERINE L. HALL,

Plaintiff,

v.

CIVIL ACTION NO. 2:12-cv-08186

BOSTON SCIENTIFIC CORPORATION,

Defendant.

**MEMORANDUM OPINION AND ORDER
(Plaintiff's Motions *in Limine*)**

Pending before the court are the following motions *in limine*: (1) Plaintiff's Motion *in Limine* No. 1 – To Exclude FDA 510(k) Evidence [Docket 143]; (2) Plaintiff's Motion *in Limine* No. 2 – To Exclude Evidence of Certain Medical Conditions of Katherine L. Hall [Docket 144]; (3) Plaintiff's Motion *in Limine* No. 3 – To Exclude Any Argument [or] Allegations of Plaintiff Being Addicted to Pain Medication [Docket 145]; and (4) Plaintiff's Motion *in Limine* No. 4 – To Exclude Social Stigmas Purportedly Associated with Stress Urinary Incontinence [Docket 146]. As further explained below, the plaintiff's Motion *in Limine* No. 1 [Docket 143] is **GRANTED**, and the plaintiff's Motions *in Limine* Nos. 2–4 [Dockets 144, 145, 146] are **DENIED**.

I. Background

This case resides in one of seven MDLs assigned to me by the Judicial Panel on Multidistrict Litigation concerning the use of transvaginal surgical mesh to treat pelvic organ prolapse (“POP”) and stress urinary incontinence (“SUI”). In the seven MDLs, there are more

than 70,000 cases currently pending, approximately 15,000 of which are in the Boston Scientific Corporation (“BSC”) MDL, MDL No. 2326. In this particular case, the plaintiff, Katherine Hall, was surgically implanted with the Obtryx Transobturator Mid-Urethral Sling System (“Obtryx”), a mesh product manufactured by BSC to treat SUI. (*See* Second Am. Short Form Compl. [Docket 109], at 3). Ms. Hall received her surgery at Gundersen Lutheran Hospital in La Crosse, Wisconsin, on October 12, 2006. (Pl. Fact Sheet [Docket 59-2], at 6). She now claims that as a result of the implantation of the Obtryx, she has developed various complications, including mesh erosion, lower abdominal pain, pelvic pressure, burning sensations, and renewed SUI. (*See id.* at 7). The plaintiff advances the following claims against BSC: negligence; strict liability for design defect, manufacturing defect, and failure to warn; breach of express and implied warranties; and fraudulent concealment. (*See* Second Am. Short Form Compl. [Docket 109] ¶ 13).¹ The instant motions *in limine* involve the plaintiff’s efforts to exclude or limit certain evidence, arguments, and testimony at trial. I address each motion in turn.

II. Motion *in Limine* No. 1 – To Exclude FDA 510(k) Evidence

First, the plaintiff moves to preclude any argument, evidence, or testimony relating to the FDA’s 510(k) clearance of any BSC product or the lack of FDA enforcement action related to such products. My reasoning for excluding evidence of the 510(k) process in general is fully set out in *Lewis v. Johnson & Johnson*, 991 F. Supp. 2d. 748, 751–52, 754–56 (S.D. W. Va. 2014), and I will not rehash it here. I will simply describe relevant Wisconsin law, which governs this case, and explain why evidence of the 510(k) process should be excluded.²

¹ By Memorandum Opinion and Order entered on February 27, 2015, [Docket 157], this court dismissed the plaintiff’s claims for manufacturing defect, strict liability for failure to warn, negligent failure to warn, breach of express and implied warranties, and fraudulent concealment. Thus, the remaining claims are strict liability for design defect and negligent design.

² The court’s choice-of-law analysis is provided in its Memorandum Opinion and Order entered on February 27, 2015, [Docket 157].

In 2011, Wisconsin codified its product liability law for claims based on strict liability. *See generally* Wis. Stat. § 895.047 (2014). Under this regime, a manufacturer is strictly liable for a defective design where (1) the product contains a design defect; (2) the defective condition rendered the product “unreasonably dangerous”; (3) the defective condition existed at the time the product left the manufacturer’s control; (4) the product reached the user without substantial changes; and (5) the defective condition caused the plaintiff’s damages. § 895.047(1). A product contains a design defect “if the foreseeable risks of harm posed by the product could have been reduced or avoided by the adoption of a reasonable alternative design by the manufacturer and the omission of the alternative design renders the product not reasonably safe.” *Id.*

In arguing for the admissibility of 510(k) evidence, BSC relies heavily on the statutory presumption set forth in § 895.047, which provides that

[e]vidence that the product, at the time of sale, complied in material respects with relevant standards, conditions, or specifications adopted or approved by a federal or state law or agency shall create a rebuttable presumption that the product is not defective.

§ 895.047(3)(b). BSC argues that its compliance with 510(k) goes to this presumption that the Obtryx is not defective, and as such, it should be admitted. I disagree. As an initial matter, 510(k) is not a “relevant standard” here. Section 895.047 concerns whether a defect rendered the product “unreasonably dangerous,” § 895.047(1), and, as the Supreme Court has held, 510(k) compliance does not go to the safety of a product.

The 510(k) process is not a safety statute or administrative regulation. The Supreme Court has determined that “the 510(k) process is focused on equivalence, not safety.” [*Medtronic, Inc. v. Lohr*, 518 U.S. 470, 493 (1996)] (internal quotation omitted); *see also Riegel [v. Medtronic, Inc.]*, 552 U.S. 312, 323 (2008)] (“While § 510(k) is focused on equivalence, not safety, premarket approval is focused on safety, not equivalence.”) (internal quotation omitted). FDA regulations also note that 510(k) clearance “does not in any way denote official approval of the device.” 21 C.F.R. § 807.97 (2012). The FDA thus prohibits manufacturers of devices cleared through the 510(k) process from

making any representations that their devices have been approved by the FDA. *See id.* (“Any representation that creates an impression of official approval of a device because of complying with the premarket notification regulations is misleading and constitutes misbranding.”). Because the FDA’s 510(k) clearance of the [product] does not speak to its safety or efficacy, it is irrelevant to this case and inadmissible under Rule 402.

Lewis v. Johnson & Johnson, 991 F. Supp. 2d 748, 755 (S.D. W. Va. 2014). Thus, observing the reasoning in *Lohr*, I **FIND** that 510(k) is not a “relevant standard,” and as such, BSC’s compliance does not trigger the presumption set forth in § 895.047(3)(b).

Similarly, BSC’s compliance with 510(k) has little relevance to the plaintiff’s claim for punitive damages. Wisconsin Statute § 895.043 provides for punitive damages when “the defendant acted maliciously toward the plaintiff or in an intentional disregard of the rights of the plaintiff.” § 895.043(3). Such conduct is not mitigated by compliance with 510(k), a regulation “intended merely to give manufacturers the freedom to compete.” *Lohr*, 518 U.S. at 492. Put differently, the fact that the Obtryx received 510(k) clearance does not make it more or less probable that BSC’s conduct in designing the Obtryx warrants punitive damages under Wisconsin law. Therefore, because 510(k) evidence is not relevant to the matter of punitive damages, it is not admissible. *See* Fed. R. Evid. 401 (“Evidence is relevant if it has any tendency to make a fact more or less probable than it would be without the evidence.”); Fed. R. Evid. 402 (“Irrelevant evidence is not admissible.”).

Even if 510(k) clearance was probative to the safety of the Obtryx or to the reasonableness of BSC’s conduct, that probative value is substantially outweighed by the risk of misleading the jury and confusing the issues. *See* Fed. R. Civ. P. 403 (providing that even relevant evidence may be excluded “if its probative value is substantially outweighed by a danger of . . . confusing the issues [or] misleading the jury”). As I explained in *Lewis v. Johnson & Johnson*,

[a] device[’s] clearance through the FDA’s 510(k) process is not relevant to state tort law. Admission of any evidence regarding the 510(k) process runs the risk of misleading the jury to believe that FDA 510(k) clearance might be dispositive of the plaintiff’s state law claims. . . . Jurors are likely to believe that FDA enforcement relates to the validity of the plaintiffs’ state law tort claims, which it does not. [Furthermore,] the jury may attach undue significance to an FDA determination, and [] alleged shortcomings in FDA procedures are not probative to a state law products liability claim.

991 F. Supp. 2d at 754–55; *see also Sanchez v. Boston Scientific Corp.*, No. 2:12-cv-05762, 2014 WL 4851989, at *35 (“[T]estimony about the requirements of the FDCA, which are not at issue in this case, could lead to more confusion about the [state law claims] than enlightenment.”). Accordingly, evidence of 510(k) clearance is **EXCLUDED** under Federal Rules of Evidence 402 and 403, and the plaintiff’s Motion *in Limine* No. 1 [Docket 143] is **GRANTED**.³

III. Motion *in Limine* No. 2 – To Exclude Evidence of Certain Medical Conditions of Katherine L. Hall

The plaintiff next moves to exclude evidence relating to a number of Ms. Hall’s medical conditions and medical procedures. (*See Mot. in Limine* No. 2 [Docket 144], at 1 (listing twelve medical conditions that, in the plaintiff’s view, should be excluded at trial)). She claims that evidence of these medical conditions is irrelevant to the injuries alleged in this case. Additionally, she argues that admitting evidence of these conditions, which may or may not be causally related to her current injuries, could create a substantial risk of jury confusion. In response, BSC asserts that the plaintiff’s medical conditions “are relevant to alternative causation and to impeach Plaintiff about the supposed timing and extent of her alleged injuries.” (BSC’s Opp. to Pl.’s Mot. *in Limine* No. 2 [Docket 150], at 1). For instance, BSC contends that the plaintiff’s kidney stones and fibromyalgia could explain several of the symptoms and pain that she now attributes to the Obtryx. (*See id.* (offering the specific causation testimony of Dr. Peter

³ Because the court has dismissed the plaintiff’s failure-to-warn claim, I need not address BSC’s argument on the relevance of 510(k) evidence in defending against that cause of action.

Finamore)). Additionally, BSC argues that the plaintiff's medical conditions go to the issue of damages, providing the jury with the evidence necessary to determine the extent to which the Obtryx is responsible for the plaintiff's alleged injuries, if at all.

I agree with BSC that the evidence at issue is relevant to the elements of causation and damages. The presence of other medical conditions could tend to make it less probable that the Obtryx is to blame for the plaintiff's injuries. *See* Fed. R. Evid. 401 ("Evidence is relevant if it has any tendency to make a fact more or less probable than it would be without the evidence . . ."). Therefore, finding the evidence relevant and seeing no risks of prejudice or jury confusion at the moment, the plaintiff's Motion *in Limine* No. 2 [Docket 144] is **DENIED**.

IV. Motion *in Limine* No. 3 – To Exclude Any Argument or Allegations of Plaintiff Being Addicted to Pain Medication

In her third motion *in limine*, the plaintiff asks the court to exclude any mention of the plaintiff "being addicted to pain medication" or "abus[ing] her pain medication" on the grounds that the admission of such evidence would result in unfair prejudice. (Pl.'s Mot. *in Limine* No. 3 [Docket 145], at 1). BSC concedes that it will not introduce evidence suggesting that the plaintiff was addicted to or abused prescription pain medications. (BSC's Opp. to Pl.'s Mot. *in Limine* No. 3 [Docket 151], at 1). Accordingly, the plaintiff's Motion *in Limine* No. 3 [Docket 145] is **DENIED as moot**.⁴

V. Motion *in Limine* No. 4 – To Exclude Social Stigmas Purportedly Associated with Stress Urinary Incontinence

Finally, the plaintiff moves to exclude "any argument, evidence, and testimony relating to certain 'social stigmas' surrounding [SUI], urge urinary incontinence, and [POP]." (Pl.'s Mot. *in*

⁴ BSC notes, however, that it does intend to introduce evidence about Ms. Hall's "lengthy use of prescription pain medication to treat her lower abdominal pain and other medical conditions in the years before receiving her Obtryx sling." (BSC's Opp. to Pl.'s Mot. *in Limine* No. 3 [Docket 151], at 1). The plaintiff does not object to this, so long as BSC does not take the next step of alleging that Ms. Hall abused or became addicted to those pain medications.

Limine No. 4 [Docket 146], at 1). These “social stigmas” include “avoidance of social activities, becoming isolated, worrying about smelling like urine, and only wearing dark clothes.” (*Id.* (citing to the expert report of Dr. Finamore)). Because Ms. Hall did not experience these stigmas, the plaintiff contends that evidence about their existence is irrelevant and could lead to jury confusion. BSC responds that, contrary to the plaintiff’s contentions, there is evidence demonstrating that Ms. Hall experienced these stigmas. (*See, e.g.*, Hall Dep. [Docket 152-1], at 24:22–23, 126:11 (testifying that she felt “embarrass[ed]” when she had episodes of incontinence)). In BSC’s view, these experiences “may have played a role in her decision to have the Obtryx implanted” and is therefore relevant to her claims against BSC. (BSC’s Opp. to Pl.’s Mot. *in Limine* No. 4 [Docket 152], at 2). Because Ms. Hall’s deposition testimony reveals that she may have experienced the stigmas to which Dr. Finamore refers, it is possible that evidence on the stigmas is relevant to her case. Moreover, I cannot ascertain the prejudicial nature of the evidence without knowing the context in which BSC will use it. Thus, I decline to exclude the challenged evidence at this time, and the plaintiff’s Motion *in Limine* No. 4 [Docket 146] is **DENIED**.

VI. Conclusion

For the reasons stated above, the plaintiff’s Motion *in Limine* No. 1 [Docket 143] is **GRANTED**, and the plaintiff’s Motions *in Limine* Nos. 2–4 [Dockets 144, 145, 146] are **DENIED**. The court **DIRECTS** the Clerk to send a copy of this Order to counsel of record and any unrepresented party.

ENTER: February 27, 2015



JOSEPH R. GOODWIN
UNITED STATES DISTRICT JUDGE